

Summary of Safety and Effectiveness
JOURNEY Unicondylar Tibial Baseplates
Smith & Nephew, Inc.

Date of Summary: October 4, 2010

Contact Person:

Gino J. Rouss, MS
Manager, Regulatory Affairs
T (901) 399-6707

Company and Address:

Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, Tennessee 38116

OCT 5 2010

Name of Device: Smith & Nephew Journey Unicondylar Tibial Baseplate

Common Name: Knee Prosthesis

Device Classification Name and Reference:

Knee joint femorotibial metal/polymer non-constrained cemented prosthesis, 21 CFR 888.3520

Device Class: Class II

Panel Code: Orthopaedics/87 HSX

Device Description

New unicondylar metal tibial baseplates have been designed and developed by Smith & Nephew Orthopaedics. In keeping with the design philosophy of the predicate Genesis Unicondylar Tibial Baseplates (K912735), the subject devices share the same design features such as:

- Shape (footprint)
- Size Offering (6 sizes with each size being offered in a RM/LL or LM/RL configuration)
- Cement Grooves
- Keel on Distal Surface

Given that the newly designed Journey tibial baseplates contain the same shape (footprint) and locking mechanism as the existing Journey Unicondylar Tibial Baseplates, the subject devices are intended to inter-lock with the currently marketed Journey Unicondylar UHMWPe Articular Inserts (K061011) in order to form a unicondylar tibial construct to replace either the medial or lateral tibial compartment of the knee.

Intended Use

The Journey Unicondylar Tibial Baseplates are indicated for restoring either compartment of a knee that has been affected by the following:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of fractures that are unmanageable using other techniques.

The implants are labeled for single use only. The tibial baseplates are designed to be implanted using bone cement.

Performance Data

Design verification testing has been performed based on requirements outlined in FDA's *Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses*, dated April 1993. Mechanical testing provided in the submission demonstrated that the Journey Unicondylar Tibial Baseplates met performance requirements and are as safe and effective as the predicate.

Mechanical testing included:

- Unsupported Baseplate Fatigue Testing; and
- Fully Supported Fatigue/Cement Adhesion Testing.

Clinical data was not needed to support the safety and effectiveness of the subject device.

Substantial Equivalence Information

The modified Journey Unicondylar Tibial Baseplates are similar to the Smith & Nephew Genesis Unicompartmental Tibial Baseplates (K912735) regarding design features, overall indications, and materials.

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted for new unicondylar metal tibial baseplates that have been designed and developed by Smith & Nephew Orthopaedics. Given that the new devices have met all performance requirements and share the same design features, overall indications, and materials as the predicates, the devices can be considered substantially equivalent to the unicondylar baseplates currently marketed under K912735.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Smith and Nephew Endoscopy, Inc.
% Mr. Gino Rouss
Regulatory Affairs Specialist
1450 East Brooks Road
Memphis, Tennessee 38116

OCT 5 2010

Re: K102069

Trade/Device Name: Smith & Nephew Journey Unicondylar Tibial Baseplates
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented
prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: July 21, 2010
Received: July 23, 2010

Dear Mr. Rouss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

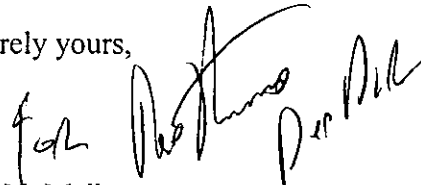
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102069

Device Name: Smith & Nephew Journey Unicondylar Tibial Baseplate

INDICATIONS FOR USE:

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- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of fractures that are unmanageable using other techniques.

The implants are labeled for single use only. The tibial baseplates are designed to be implanted using bone cement.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jonathan J. for MCM
(Division Sign-off)
Division of Surgical, Orthopedic,
and Restorative Devices

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